

Execution

Minimum of tests (Level 1) performed on designed eCRF should be based on:

- **Requirement of entering the value** – checking if the data needed to be entered is possible to be entered in a particular field
- **Format of values** - checking, if all variables are of expected format
- **Range checks** – checking if all variables are of expected ranges by using tests for values, which are:
 - within expected range (approximately central value between two extremes)
 - within expected range, but close to the extreme values
 - within expected range, equal to extreme values
 - beyond expected range, but very close to the expected extreme values
 - far beyond expected range at both sides of extremes
- **Negative value check** – to assess if any numeric data is not negative
- **Future Date Checks** – to evaluate if the data fields forbid entering future dates
- **Multiple data fields** – to check, if the fields that should be repeating during the study, work properly within different visits (i.e. Concomitant Medications, Adverse Events)
- **Duplicated data** – to assess if any field was double-added incorrectly to the eCRF
- **Auto-queries** – checking, if all queries set while designing auto-queries appear in the right position, under the proper circumstances
- **Confirmation of logic between particular fields** – checking if all logic conditions are valid and work properly
- **Regression testing** – checking, if changes in the structure of tested eCRF will not damage other parts of the system
- **Comparing extracted data to the original data** – checking, if the data downloaded from the tested database, is the same as the original data, entered to the eCRF

Additional tests (Level 2) of User Acceptance Testing should include:

- **Personal data protection evaluation** – to check, if all data entered into the eCRF are prevented from possibility of patient identification
- **Correction of lab values units and ranges** – checking, if the lab values units in eCRF are correctly counted into standard international units, and if their lower and upper range values are compatible with standards
- **Patient ID Number check** – to evaluate if each patient has unique ID number, consistent with the numbering set up while designing the eCRF
- **Unscheduled, Follow-up visits check** - to assess if designed database contains appropriate forms to manage with Unscheduled of Follow-Up visits, covered in the protocol.

 **SOP 38b Associated Document 3 - User Acceptance Testing**

The following has been taken from SOP 38b AD 3, for more information please click [here](#)